

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1682]

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**Agency Information Collection Activities; Proposed Collection; Comment Request;
Radioactive Drug Research Committee**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to radioactive drugs used in research.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Radioactive Drug Research Committee—21 CFR 361.1 (OMB Control Number 0910–0053)—
Extension**

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research. The regulations in § 361.1 (21 CFR 361.1) set forth specific regulations regarding the establishment and composition of the Radioactive Drug Research Committees and their role in approving and monitoring research studies utilizing radiopharmaceuticals. No study involving any administration of a radioactive drug to research

subjects is permitted without the authorization of an FDA-approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

The regulations in § 361.1(c)(2) require that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, and for each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under section 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)). Types of research studies not permitted under this regulation are also specified, and include those “intended for (the) immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).” These studies require filing of an investigational new drug application under 21 CFR 312.1 and

the associated information collections are covered under OMB Control No. 0190-0014, which expires December 31, 2002.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three committee chairpersons who were selected from different geographical areas and of varying levels of Radioactive Drug Research Committee membership and activities. These chairpersons were asked for their assessment of time expended, cost, and views on completing the necessary reporting forms.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

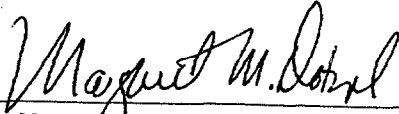
21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914 FDA 2915	96	1.0	96	1	96
361.1(c)(3)		63	5	315	3.5	1,103
361.1(d)(5)		63	5	315	0.1	31
361.1(d)(8)		63	5	315	0	0
Total						1,230

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Form	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
361.1(c)(2)	FDA 2914 and 2915	96	1 per quarter	10	960
Total			4 per year		960

Dated: December 27, 2000

OC00323



Margaret M. Dotzel,
Associate Commissioner for Policy,

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[FR Doc. 00-¹???? Filed ??-??-00¹; 8:45 am]

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